

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:) Examiner: Afremova, Vera
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 Liu et al.) Group Art Unit: 1657
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 Serial No.: 10/574,163)
) Docket No.: 8028-005-US
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 Filed: March 29, 2006)
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 For: IMMORTALIZED HEPATOCYTES)
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SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Mail Stop: Amendment
Honorable Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

This document is a Supplemental Information Disclosure Statement to the above-cited patent application.

Attached is at least one form PTO/SB/08A/B listing documents believed relevant to the subject application. The submission of the following information is not intended, nor should it be construed, to constitute an admission that any patent, article, or other information referred to herein is "prior art" unless specifically designated as such. In accordance with 37 C.F.R. § 1.97(b), the filing of this information shall not be construed to mean that a search has been made or that no other material information may exist. Neither should its submission be construed to indicate that a thorough search should not be conducted by the Examiner.

It is believed that this disclosure complies with the requirements of 37 C.F.R. § 1.96, § 1.97, and § 1.98 and the Manual of Patent Examining Procedures § 707.05(b). If for some reason the Examiner considers otherwise, it is respectfully requested that the undersigned be telephoned at (858) 450-0099 so that any deficiencies can be remedied.

This Supplemental Information Disclosure Statement is being submitted before the mailing date of an Office Action on the merits for the above-identified patent application. Accordingly, no fee is due for the filing of this Information Disclosure Statement under 37 C.F.R. § 1.97(b)(2). Additionally, each item of information contained in this Supplemental Information Disclosure Statement was first cited in a communication from a foreign patent office, namely the European Patent Office, in a counterpart foreign application not more than three months prior to the filing of this Supplemental Information Disclosure Statement, pursuant to 37 C.F.R. § 1.97(d) and 37 C.F.R. § 1.97(e). The communication from the European Patent Office was mailed on December 18, 2006 and was a supplementary European search report. Therefore, even if an Office Action on the merits has been mailed for the above-identified patent application, no fee is due for the submission of this Supplemental Information Disclosure Statement.

A copy of each document is enclosed, except for issued United States patents and published United States patent applications pursuant to 37 C.F.R. § 1.98(a)(2)(ii). Some of the documents may have markings thereon. No significance is to be attached to the markings. These documents are not necessarily analogous art. Additionally, the order of the following documents is to be accorded no particular import, as the order thereof is completely fortuitous.

It is respectfully requested that these documents be: (1) fully considered by the Patent and Trademark Office during the prosecution of this application; and (2) represented on any patent which may issue on the application. Applicant respectfully

requests that copies of the forms PTO/SB/08A/B, as considered and initialed by the Examiner, be returned with the next communication.

A publication, J.H. Lee et al., "Production and Characterization of Immortalized Rat Hepatocytes Secreting Hepatocyte Growth Factor/Scatter Factor," Hepato-Gastroenterology 47: 978-983 (2000).

A publication, L.J. Schippers et al., "Immortalized Human Hepatocytes as a Tool for the Study of Hepatocytic (De-)Differentiation," Cell. Biol. Toxicol. 13: 375-386 (1997).

A publication, K. J. Allen et al., "Conditionally Immortalized Mouse Hepatocytes for Use in Liver Gene Therapy," J. Gastroenterol. Hepatol. 15: 1325-1332 (2000).

An Internet publication, "Immortalized Hepatocytes: A New *In Vitro* Approach to Enzyme Induction Studies," Xenotechniques 1: 1-11 (2003), at http://www.xenotechllc.com/library/downloads/xenotechniquesv01_1_no_1_2003.pdf.

A publication, A.M.A. Pfeifer et al., "Simian Virus 40 Large Tumor Antigen-Immortalized Normal Human Liver Epithelial Cells Express Hepatocyte Characteristics and Metabolize Chemical Carcinogens," Proc. Natl. Acad. Sci. USA 90: 5123-5127 (1993).

A publication, N. Kobayashi et al., "Prevention of Acute Liver Failure in Rats with Reversibly Immortalized Human Hepatocytes," Science 287: 1258-1262 (2000).

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A publication, J.B. Mills et al., "An HTS Assay for Induction of Enzymes and Transporters Using a Human Hepatocyte Clonal Line and RNA Detection," Drug Metab. Rev. 34 (Suppl. 2): 124 (2002).

A publication, J. Liu et al., "Characterization and Evaluation of Detoxification Functions of a Nontumorigenic Immortalized Porcine Hepatocyte Cell Line (HepLiu)," Cell Transplant. 8: 219-232 (1999).

A publication, J. Liu et al., "Growth and Metabolic Activity of Activity of Immortalized Porcine Hepatocytes in Extracorporeal Hollow-Fiber Liver Assist Devices," Artificial Organs 25: 539-545 (2001).

A publication, A.L. Morris et al., "In Vitro Induction of Cytochrome P450S and Drug Transporters Using the Fa2N-4 Immortalized Human Hepatocyte Line," Drug Metab. Rev. 35 (Suppl. 2): 125 (2003). This publication was published after the relevant priority date for the above-identified patent application and is not prior art; it is included solely for completeness.

A publication, C. Woods et al., "Induction of Genomic Instability in SV40 Transformed Human Cells: Sufficiency of the N-Terminal 147 Amino Acids of Large T Antigen and Role of pRB and p53," Oncogene 9: 2943-2950 (1994).

Respectfully submitted,



Date: January 23, 2007

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